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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,455	02/09/2001	Tarun K. Dhar	056859/0115	6699

22428 7590 04/04/2005

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,455

Applicant(s)

DHAR ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-10,12-20 and 44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-10,12-20 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgement is made of the submission dated 18 January 2005. Claims 2, 7, 11, 21, 45 and 46 have been canceled. Claims 22-43 have been withdrawn. Claims 1, 3-6, 8-10, 12-20 and 44 are pending.
2. The text of those 35 US Codes not found in this action may be found in a previous office action.

Claim Rejections - 35 USC § 112

3. Claims 1, 3-6, 8-10, 12-20 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, as amended, is more appropriately claim as a kit or a system comprising different components. Not all of the components recited in claim 1 are physically connected to each other prior to use. Specifically, the absorbent body is recited as being provided separate from the device, therefore, the absorbent body is clearly not part of the device of claim 1, thus, it appears that Applicant is attempting to present a claim to different inventions.

The method of using the absorbent material recited in claim 1 is not afforded patentable weight because a recitation of the intended use of the absorbent body must result in a structural difference between the claimed absorbent body and the absorbent body of the prior art in order to patentably distinguish the claimed absorbent body

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from the prior art. If the prior art absorbent body is capable of performing the intended use, then it meets the claim.

Claim 1 is also confusing because it is unclear how the absorbent material is placed between the reaction membrane and the support when the reaction membrane is recited as being glued or taped to the support. Even though it appears that only a portion of the reaction membrane is glued to the support, the claim does not make clear which portion or if openings are available in order to insert the absorbent body in between the reaction membrane and the support. Language such as those on page 16, lines 15-20, and page 17, lines 29-31 will more clearly define the relationship between the various components of claim 1.

Claims 6 and 8 are vague because they depend on canceled claim 2.

The recitation of "the narrow solid-strip thickness" in claim 6 lacks antecedent support.

The recitation of "the bottom support layer with adequate mechanical strength" in claim 15 lacks antecedent support.

Claim 20 is confusing because it is unclear how the absorbent body is placed between the reaction membrane and the support when the reaction membrane has been glued to the support.

Claim Rejections - 35 USC § 112

4. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 20, as amended, further limit claim 1 from which it depends by placing the absorbent body in the analytical device instead of reciting it as a separate component. Therefore, claim 20 is seen as being directed toward a device comprising a reaction membrane having antigens or antibody spotted thereon positioned on top of an absorbent material and fixed to a support layer. Such a device does not have support in the specification as originally filed. The specification on pages 13-15 discloses a device comprising a reaction membrane having antigens or antibody spotted thereon and is attached to a solid support layer. The absorbent bodies are recited as being provided separate from the analytical device. The specification also teaches that the absorbent bodies are assembled to the device during an assay. Nowhere in the specification is there a disclosure of a final product comprising the device as claimed in claim 20.

Applicant is required to cancel the new matter in response to this rejection.

Claim Rejections - 35 USC § 103

5. Claims 1, 3-6, 8-10, 12-19 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al (US 5,807,522) in view of Lin et al (US 6,265,176) and Bhattacharya et al (Journal of Immunological Methods. 227:31-39. 1999).

Brown discloses a substrate formed of a water-impermeable backing having thereon a porous membrane. The porous membrane is applied to the backing by a variety of methods including heat-seal stamping, laminating or via adhesives (column 12). Ligands such as antigen or antibody are applied in a spotted array onto the membrane (columns 6 and 15).

Brown differs from the instant invention in failing to teach a body of absorbent material provided separately nor does Brown teach the use of electron-rich blocking proteins.

Lin, however, discloses analytical test kits and method comprising test cards or strips of an inert plastic carrier having a flat, non-absorbent surface having antigen or antibody spotted thereon. The spots on the card may be more than one reagent for testing for multiple unknowns. During use, the spot is washed and blotted dry using absorbent blotting papers. Lin teaches test kits comprising the carrier and blotting papers.

Bhattacharya discloses the use of electron-rich blocking proteins such as p-hydroxy-phenylpropionic acid-casein conjugates and p-hydroxy-phenylpropionic acid-gelatin conjugates as blocking agents. Bhattacharya teaches that such blocking agents

provide the advantage of an increase in sensitivity and increased the detection limits in ELIZA.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the blotting papers taught by Lin in the test system and kit of Brown because such blotting papers are well known in the art. The use such blotting papers provides the advantage of a shorter assay time because test cartridges may be blotted dry instead of air dry thus reducing the time needed and optimizing assay conditions. It also would have been obvious to replace the blocking agents taught by Brown with those of Bhattacharya for the advantages stated above. Even though the blotting papers of Lin has a different use from the absorbent body of the instant invention, Lin make obvious the inclusion of such papers in the test kit of Brown because the intended use of the absorbent body does not result in a structural difference between the claimed absorbent body and the blotting papers of Lin. They are both made of absorbent paper.

6. Claims 1, 3-6, 8-10, 12-15, 18-19 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearns et al (US 5,573,919) in view of Lin et al (US 6,265,176) and Bhattacharya et al.

Kearns discloses an assay for detecting analyte comprising an absorbent membrane contained in a casing made of plastic. The absorbent membrane has porosity such that it can retain particles having a size of about 0.1 micron to 10 microns. See

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column 2, line 41 through column 2, line 11; and column 3, lines 17 through column 4, line 17. Kearns teaches coating the surface with BSA to prevent non-specific binding. See column 6, lines 8-20 and 44-57.

Kearns differs from the instant invention in failing to teach a body of absorbent material provided separately and the use of electron-rich blocking agents.

See the discussion of Lin and Bhattacharya above.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the blotting papers taught by Lin in the test system and kit of Kearns because such blotting papers are well known in the art. The use such blotting papers provides the advantage of a shorter assay time because test cartridges may be blotted dry instead of air dry thus reducing the time needed and optimizing assay conditions. It also would have been obvious to replace the BSA blocking agent taught by Kerns with the electron-rich blocking agents of Bhattacharya for the advantages stated above.

Response to Arguments

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion


8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
3/30/05